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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,462	05/26/2000	Stephen Fox Heinemann	SALK1590-3	2034
30542	7590	11/14/2003	EXAMINER	
FOLEY & LARDNER			U.L.M., JOHN D	
P.O. BOX 80278			ART UNIT	
SAN DIEGO, CA 92138-0278			PAPER NUMBER	

1646

DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application N .</b> 09/580,462	<b>Applicant(s)</b> HEINEMANN ET AL.	
	<b>Examiner</b> John D. Ulm	<b>Art Unit</b> 1646	

-- Th MAILING DATE of this communication app ars on the cover sheet with th correspond nce address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 and 34-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

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1) Claims 7 and 34 to 44 are pending in the instant application. Claims 7, 34, 36, 37, 39 and 42 have been amended as requested by Applicant in the correspondence filed 25 August of 2003.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) The figures filed on 03 December of 2002 are objected to under 37 C.F.R. § 1.84(U)(1), for those reasons of record in section 2 of Paper Number 6. Applicant urges that the replacement drawings filed with the communication "dated 10/3/02" meets the requirements of 37 C.F.R. § 1.84(U)(1). First, Applicant is advised that there is no communication of record in the instant application that was filed on 03 October of 2003. There is a set of drawings of record that was filed on 03 December of 2003 but the drawings in that set do not comply with 37 C.F.R. § 1.84(U)(1) because they employ figure numbers such as "7B(1)". **Correction is required.**

5) Claims 7 and 34 to 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims are not enabled because they make references to nucleotide and amino acid sequences in figures that do not contain sequences. One of ordinary skill in the art, for example, can not make a substantially pure DNA having the nucleotide

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sequence shown in Figures 9(A), 9(B) and 9(C), as required by claim 7, when Figures 9(A) and 9(B) do not depict sequences and there is no Figure 9© in the instant application.

Further, claim 39 is now a single means claim since it encompasses a pure polynucleotide that encodes a functionally defined protein in the absence of any physical limitations. Because any polynucleotide will hybridize to any other polynucleotide under some set of conditions, the hybridization limitations to the claimed polynucleotide are meaningless. Therefore, this claim encompasses a pure polynucleotide “encoding a beta2 subunit of a neuronal acetylcholine receptor” “not binding acetylcholine. A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt , 708 F.2d 712,>714 - 715,< 218 USPQ 195>, 197< (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a)

6) Claim 35 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for those reasons of record in section 8 of Paper Number 13. Applicant has traversed

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this rejection of the premise that the text from line 30 on page 16 to line 27 on page 17 of the instant specification contains the assertion "that all restrictions on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent". The text referred to by Applicant is reproduced below:

#### DEPOSITS

cDNA clones comprising neuronal nicotinic acetylcholine receptor genes alpha2 (clone pHYPI6), alpha3 (clone pPCA48), alpha4.1 (clone pHYA23-I(E)I) # alpha4.2 (clone pHIP3C(E)3), alpha5 (clone Pcl321), beta2 (clone pPCX49), beta3 (clone ESD76) and beta4 (clone pZPCI3), all of which are in E.coli HB101, have been deposited at the American Type Culture Collection, Rockville, Maryland, U.S.A. (ATCC) under the terms of the Budapest Treaty on the International Recognition of Deposits of Microorganisms for Purposes of Patent Procedure and the Regulations promulgated under this Treaty. Samples of the cloned genes are and will be available to industrial property offices and other persons legally entitled to receive them under the terms of said Treaty and Regulations and otherwise in compliance with the patent laws and regulations of the United States of America and all other nations or international organizations in which this application, or an application claiming priority of this application, is filed or in which any patent granted on any such application is granted. The ATCC Deposit Numbers for the eight deposits are as follows:

alpha2	clone PHYPI6	ATCC No. 67646
alpha3	clone pPCA48	ATCC No. 67642
alpha4.1	clone pHYA23-I(E)I	ATCC No. 67644
alpha4.2	clone pHIP3C(3)	ATCC No. 67645
alpha5	clone Pcl321	ATCC No. 67652
beta2	clone pPCX49	ATCC No. 67643
beta3	clone EDS76	ATCC No. 67653
beta4	clone PZPCI3	ATCC No. 67893

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Nowhere does the assertion “that all restrictions on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent” appear in the text referred to by Applicant.

7) Claims 7 and 34 to 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7.1) Claims 7 and 34 to 41 are vague and indefinite because there is no antecedent basis for “the nucleotide sequence set forth in Figures 9(A), 9(B) and 9(C)”.

7.2) Claims 42 to 44 are confusing because the amino acid sequences of the subunits recited therein do not appear in the figures recited therein.

7.3) Claims 34 to 44 are vague and indefinite in reference to the term “beta2” for those reasons of record as applied to claims 5 to 9, 11, 12, 14 to 27 in section 7 of Paper Number 6 and claims 5, 6, 8, 9, 11, 12, 14 to 27, 31 and 32 in section 9.2 of Paper Number 8. Applicant’s traversal of this rejection essentially restate those arguments of record which have been previously answered.

7.4) Claims 42 to 44 are vague and indefinite because each of the limitations “50% amino acid sequence identity”, “44% amino acid sequence identity” and “64% amino acid sequence identity” requires a reference to one or more specific amino acid sequences. The limitations “alpha2, alpha3, alpha4 and alpha5”, “beta3” and “beta4” do not correspond to specific amino acid sequences. Further, because the instant specification does not identify that

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property or combination of properties which is unique to and, therefore, definitive of an alpha2, alpha3, alpha4, alpha5, beta3 or beta4 receptor subunit, it is not possible to determine the metes and bounds of these claims.

8) Applicant's arguments filed 25 August of 2003 have been fully considered but they are not persuasive.

9) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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